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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,607	02/11/2002	Rozlyn A. Krajcik	4555-43U1	5919

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EXAMINER

KIM, JENNIFER M

ART UNIT PAPER NUMBER

1617

DATE MAILED: 12/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/073,607	Applicant(s) KRAJCIK ET AL.	
	Examiner Jennifer Kim	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-12 and 20-44 is/are pending in the application.
- 4a) Of the above claim(s) 9-12 and 20-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/3/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on October 3, 2005 has been entered.

Action Summary

The rejection of claims 31- 37 under 35 U.S.C. 103(a) as being unpatentable over Drug Launches (6 June 1988) is being maintained for the reasons stated in the previous office action.

The rejection of claims 38-44 under 35 U.S.C. 103(a) as being unpatentable over Drug Launches as applied to claims 31-37 above, and further in view of Lurie (U.S.Patent No. 6,075,005) is being maintained for the reasons stated in the previous office action.

Allowable Subject Matter

Claim 35 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicants' arguments filed October 3, 2005 have been fully considered but they are not persuasive. Applicants argue chlorhexidine is more appropriately characterized as a bisbiguanide by shown in the Exhibit B. This is not persuasive because Applicants' claim limitation of the structure of the compound being "biguanide" does not exclude "bisbiguanides". It is the Examiner's position that the Instant specification provides **no structural guidance** of the biguanide compounds which are qualified for having an insulin sensitivity increasing substance (ISIS) and no **such structural guidance** was given in instant case, envisioned **functional limitation** (an insulin sensitivity increasing substance) does not distinguished the same (biguanide) compound utilized for the same effect (treatment of alopecia) taught by the prior art. Applicants argue that chlorhexidine is an antiseptic or disinfectant antimicrobial function is based on its chlorinated phenyl rings, part of a structure which is considerably different from the structure of metformin and the exemplary biguanide compound mentioned through the application and its examples, having a structure shown in Exhibit C, having different activity in Exhibit D

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and that Exhibits G, H and I demonstrate that chlorohexidine interferes with sugar transport and metabolism and it is not a characteristics of an ISIS. This is not persuasive because the instant specification provides no structural guidance of the biguanide compounds in general. Accordingly, the instant specification and the claims do not eliminate the compound having biguanide structure of chlorohexidine. Applicants argue that the date of the commercial availability of Novian Forte was June 1988 but there is no evidence of commercial availability of Novian Forte in the United States. This is not persuasive because the product, Novian Forte, is well known by the public since 1988. Therefore it would have been obvious to one of ordinary skill in the art employ the product for the stimulation of hair growth and prevention of hair loss as taught by the Drug Launches since 1988. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

It is suggested to draw claims to specific biguanide compound, metformin, only taught by the instant specification to accelerate the prosecution.

In view of the above Office Action of December 28, 2004 is deemed proper and asserted with full force and repeated herein to obviate applicants' claims.

Claim Rejections - 35 USC § 103

Claims 31- 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drug Launches (6 June 1988).

Drug Launches teaches chlorohexidine (biguanide compound) is commercially available in a liquid formulation of 150ml, for the stimulation of hair growth and prevention of hair loss.

The prior does not expressly teach the administering to the mammal (human) and the active agent to reach an affected area of pilosebaceous apparatus.

It would have been obvious to one of ordinary skill in the art to employ chlorohexidine formulation taught by Drug Launches in mammal for the treatment of alopecia because chlorohexidine formulation is commercially available for the stimulation of hair growth. One would have been motivated to employ the chlorohexidine formulation for the treatment of alopecia in order to achieve the therapeutic benefit of stimulation of hair growth in a mammal having alopecia condition. Moreover, the active agent (biguanide compound) taught by Drug Launches obviously reaches an affected area of a pilosebaceous apparatus upon administration to effectively stimulate the hair growth as taught by Drug Launches. Absent any evidence to contrary, there would have been a reasonable expectation of success in treating alopecia by preventing hair loss in mammal with easy access commercially available product taught by Drug Launches. The pharmaceutical formulations, e.g., topical, oral

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are all deemed obvious since they are all within the knowledge of the skilled pharmacologist and represent conventional formulations.

Claims 38-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drug Launches as applied to claims 31-37 above, and further in view of Lurie (U.S. Patent No. 6,075,005).

The teachings of Drug Launches as applied as before.

Drug Launches does not teach the combination of chlorohexidine composition with STI, ARB or the activity-enhancing agent.

Lurie teaches anti-androgenic agents such as finasteride, spironolactone, flutamide or RU 58841 is useful for the treatment of hair growth or alopecia. (abstract).

It would have been obvious to one of ordinary skill in the art to combine STI, ARB with biguanide compound taught by Drug Launch because all the components are well known individually for treating alopecia. It would be expected that the combination of components would treat alopecia conditions involving hair loss as well. The motivation for combining the components flows from their individually known common utility (see In re Kerkhoven, 205 USPQ 1069(CCPA 1980)). Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sreenivasan Padmanabhan
Supervisory Examiner
Art Unit 1617

Jmk
December 27, 2005

SHENGJUN WANG
PRIMARY EXAMINER